

**Significant Analysis**  
**Rules Concerning Kidney Dialysis Treatment Centers**  
**Revision of WAC 246-210-010 and 280**  
**July 2006**

**Introduction:**

The Department of Health's office of Facilities and Services Licensing operates the Certificate of Need (CON) Program. The CON process is designed to ensure that patients have access to the highest level of care at the lowest reasonable cost. Kidney disease treatment center providers must receive a CON to become certified as a provider of services. Applications are submitted to the Department of Health and are evaluated using a prescribed methodology. The existing methodology was developed in 1990 and last revised in 1996.

The department formed the End Stage Renal Disease (ESRD) Stakeholders Committee in 2004 to reach consensus on revisions to the rules governing the awarding of a Certificate of Need to providers of kidney dialysis and related services. The committee discussed: a) alternative methods for forecasting future need; b) the planning areas that guide decisions about methodology and service provision; c) concurrent review, the process by which the department comparatively reviews applications by two or more providers to serve the same area and constituency; d) the methodology and standards for determining and achieving an efficient level of utilization of existing facilities before applications to expand them or construct new ones can be approved by the state; and e) the “tie-breaking” criteria used by the state to award additional stations or approve new facilities when proposals by two or more applicants indicate that the applicants would provide the same level of quality care to the same group of patients.

The ESRD Stakeholders Committee met twice in 2004 before adopting an “interest-based” negotiations process in early 2005. Between 12 January and 7 December 2005, the Committee met eight times. Subcommittees of the larger group met an additional four times. A consultant was hired to assess two methodologies for forecasting future need, linear and non-linear regression analysis. Committee members worked between meetings to conduct research, develop alternatives and propose solutions to their fellow members.

As part of the revision process, the department is required by RCW 34.05.328 to conduct an analysis of the proposed changes, including an evaluation of the probable benefits and costs. The department has determined that the probable benefits of the proposed rule are greater than its probable costs and that the rule being adopted is the least burdensome alternative for those required to comply with it. These rules impose no cost to the applicant; the rules prescribe the methodology by which the department will evaluate applications for Certificate of Need review. The rules will benefit the public by assuring that applications for kidney dialysis treatment facilities are reviewed using the most recent data and continue to reflect the ongoing changes in the health care environment.

**Briefly describe the proposed rule.**

The proposed rule prescribes the methodology for predicting the future need for kidney dialysis services, and the processes and practices by which the Certificate of Need Program awards CONs to applicants who propose to provide these services.

**Is a Significant Analysis required for this rule?**

The proposed rule defines the process and practices the department will apply to Certificate of Need applications for kidney dialysis treatment centers. Portions of this rule require a significant analysis. However, DOH has determined that no significant analysis is required for the following portions of the rule.

WAC rules with no significant impact	Justification
246-310-010 Definitions	RCW 34.05.328(5)(b)(iv) Clarification
246-310-280 Kidney Dialysis Treatment Centers - Definitions	RCW 34.05.328(5)(b)(iv) Clarification

**A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.**

The program is authorized in RCW 70.38, Health Planning and Development, and is responsible for reviewing proposals to provide specific types of health services, including kidney disease treatment centers. The purpose of the CON program is to "promote, maintain, and assure the health of all the citizens in the state, to provide accessible health services, health manpower, health facilities, and other resources while controlling excessive increases in costs." The statute also states that health planning "should be concerned with public health and health care financing, access and quality, recognizing their close interrelationship and emphasizing cost controls of health services, including cost effectiveness and cost-benefit analysis."

**B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.**

The rule prescribes the methodology for predicting the future need for kidney dialysis treatment centers, and the processes and practices by which the department awards CONs to applicants who propose to provide these services. Stakeholders agreed that rulemaking was in order in order to ensure clear, predictable, consistent and timely decisions. Rulemaking assures applicants and affected parties that decision-making is clearly delineated in advance to the applicants. Without rules, the department could be criticized for not applying criteria fairly and equitably.

**C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.**

The portions of the rule that are significant are analyzed in the numbered list below. As discussed above, other portions of the rule are not significant and are therefore not included in this analysis.

*1. WAC 246-310-280(8) Kidney disease treatment centers --Definitions--"planning area boundaries"*

Description: Each county is a separate planning area, except for the planning sub-areas identified for King, Snohomish, Pierce and Spokane counties. These sub-areas are divided by zip code.

Analysis: This rule does not impose a cost. The rule benefits the public because it increases the number of planning areas. Size and location of planning areas are important for achieving the interest of the state and providers in making services accessible and convenient for consumers, and for achieving the providers' interest in conducting long-range planning that enables them to offer high quality services delivered efficiently and expeditiously. The rule is also flexible because it allows for flexibility when the United States Postal Service changes zip codes. The establishment of planning area boundaries in rural areas will encourage the development of facilities in those areas to improve patient access to care.

*2. WAC 246-310-282 Kidney disease treatment centers--Concurrent review cycle*

Description: Kidney disease treatment center applications will be reviewed using a concurrent review cycle. Concurrent review is the process by which competing applications to provide service in the same service area are reviewed simultaneously by the department, with the department comparing them to each other and applying the adopted rules to award Certificates of Need. There are four concurrent review cycles each year; a cycle begins in January, April, July and October. The department is required to complete a concurrent review within nine months, and a regular review within six months. If the deadline cannot be met, the department is required to notify the applicants 15 days prior to the scheduled decision date. If an application is submitted under a concurrent review cycle does not compete with another application, the department may convert it to a regular review process.

Analysis: There is no cost associated with this rule. The rule is a benefit because a concurrent review cycle will assist the department to produce timely decisions that are based on consistent application of the rules, with a minimal amount of individual discretion for interpreting them; an accurate understanding and support of the process by all participants; and improving and maintaining excellent relations between the CON program and the stakeholders. RCW 70.38.115 recognizes concurrent review for the purpose of comparative analysis and evaluation of competing or similar projects in order

to determine which of the projects may best meet identified needs. Concurrent review is currently used for projects such as open heart surgery, pediatric cardiac surgery, hospice, hospice care centers, nursing homes, and continuing care retirement communities. Data used to project station need will be the most recent quarterly data available from the Northwest Renal Network as of the first day of the application submission period. Each application will be reviewed using the same data and criteria to ensure clarity, fairness and consistency for the applicant and the department's review of the application.

*WAC 246-310-284 Kidney disease treatment centers --Methodology*

Description: Projected station need will be based on 4.8 resident in-center patients per station for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens and Wahkiakum counties. The projected station need for these planning areas will be 3.2 resident in-center patients per station. If a planning area has experienced less than six percent growth in the previous five years, linear regression will be used to project station need. If a planning area has experienced six percent or greater growth in the previous five years, nonlinear (exponential) regression will be used to project station need. Before new in-center kidney dialysis stations will be approved, all facilities in the planning area must be operating at 4.8 patients per dialysis station for all planning areas except those exception planning areas listed above, which must be operating at 3.2 in-center patients per station.

Analysis: There is no cost associated with this rule. The rule clarifies which type of regression should be used, depending on growth rates. The committee engaged a consultant to analyze whether linear or non-linear (exponential) regression should be used for projecting future need. The committee agreed that linear regression should be used by service providers to calculate the need for future stations in a planning area when that planning area has experienced less than six percent growth in each of the previous five years; non-linear (exponential) regression should be used when a planning area has experienced six percent or more growth during that period. Both methods of predicting need are self-correcting and the use of either one will not lead to incorrect or indefensible conclusions. It is not really possible to argue that one method is better than another, but it appears that in certain situations linear regression analysis may be more appropriate, while in other situations exponential regression may be more appropriate. Situations in which one method is more appropriate than the other is related to growth rates. Linear regression analysis is simpler and less susceptible to variations, offers a narrower range of choices and describes the overall trends or growth rates a little more accurately. When year-to-year growth rates reach ten percent or more, exponential analysis appears to more accurately estimate a community's need. This process is beneficial because it is designed to be sufficiently flexible to reflect differences among communities to meet patient needs. It ensures reliable, cost-effective planning that achieves patient and community needs and provides clear expectations of and criteria by which are evaluated.

The proposed rule allows for more flexibility and access than the current rule because new station need in rural areas will be determined using two-patient shifts (3.2 patients

per station) instead of three patient shifts (4.8 patients per station) used for the more urban areas.

*WAC 246-310-286 Kidney disease treatment centers--Standards for planning areas without an existing facility*

Description: As of this date, Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Pacific, Pend Oreille, San Juan, Skamania, Stevens and Wahkiakum planning areas do not have an existing kidney dialysis facility. The department will award the first appropriate approvable project proposing to establish a facility in one of these planning areas a minimum of four stations. The facility must be projected to operate at 3.2 patients per station by the third full year of operation.

Analysis: There is no cost associated with this rule. This rule is a benefit because it increases access to services for the public. This rule is intended to encourage providers to establish centers in rural communities that do not have existing centers, while assuring quality services by requiring appropriate operating levels. Currently, some dialysis patients must travel long distances in order to access services.

*WAC 246-310-288 Kidney disease treatment centers--Exceptions and tiebreakers*

If two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved, the department will use tiebreakers to determine which application or applications will be approved. The department will approve the application accumulating the largest number of points. If sufficient additional stations remain after the approval of the first application, the department will approve the application accumulating the next largest number of points, not to exceed the total number of stations projected for a planning area. Tiebreakers include provision of training services, private rooms for isolating patients, permanent bed stations, evening shifts, meeting the projected need, economies of scale, historical providers, geographical access and provider choice. If applications remain tied after applying all the tiebreakers, the department will award stations as equally as possible among the applications without exceeding the total number of stations projected for a planning area.

Analysis: There is no cost associated with this rule. Tiebreakers are used by CON staff to determine which applicant should be awarded a Certificate of Need when the applications of two or more providers have been deemed of equal merit by staff. The committee recommended that four criteria that should be used in decision making are need, financial feasibility, quality of care and cost containment. Members agreed that "need" should be more specifically defined to include the range of services available or accessible to patients. This means that the department will determine if an applicant offers a range of options (such as home dialysis or three shifts per day) to make services more available or accessible to patients. If competing applications remain tied after all tiebreakers are applied, stations will be awarded as equally as possible among the applicants. This rule provides clarity and consistency for applicants because they will

know how stations will be awarded in the event of a tied decision. The public will benefit from having access to the best available services.

*WAC 246-310-289 Kidney disease treatment centers--Relocation of facilities*

Description: A health care facility relocating in the same planning area is not considered to be a new facility if the existing facility ceases operation, no new stations are added, there is no break in service, the facility has been in operation for at least five years at its present location and it has not been purchased, sold or leased within the last five years.

Analysis: This rule does not impose an additional cost. The committee agreed that relocating a facility to another planning area meets the definition of establishing a new facility. The rules do not require a new Certificate of Need if a provider is replicating the existing facility. The proposed rules ease the burden and allow flexibility for those facilities relocating within the planning area.

**D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.**

DOH staff worked closely with constituents and the public to minimize the burden of this rule. Many meetings were held with the committee. Mutual interests were identified and considered throughout its deliberations. The rules are not intended to impose a burden upon the applicant, but to prescribe decision-making criteria that the department will use when evaluating applications. In the course of these and other efforts, the following alternative version(s) of the rule were rejected:

*Alternative version #1: Regression Analysis*

The subcommittee spent much time, and engaged a consultant, to analyze whether linear regression or exponential (non-linear) regression is the most appropriate method for projecting future need. Previously, the applicant might use either method. Rather than using one method or another, it was decided that linear regression should be used by service providers to calculate the need for future stations in a planning area when that planning area has experienced less than six percent growth in each of the previous five years. Exponential (non-linear) regression should be used by service providers to calculate the need for future stations in a planning area when that planning area has experienced six percent or more growth in each of the previous five years. Compared to this alternative version, the proposed rule is less burdensome for those required to comply with it because applicants will know which type of analysis applies to estimate a community's need.

*Alternative version #2: Planning areas*

The committee considered if planning areas should remain unchanged to be consistent with the remainder of the Certificate of Need methodologies, or be revised to achieve accessibility and convenience for consumers, and for achieving the providers' interest in conducting long-range planning that enables them to offer high quality services delivered efficiently and expeditiously. The committee chose to revise the planning areas, which is less burdensome for the applicants because in rural areas they do not have to demonstrate need, but an interest in serving the area.

**E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.**

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

**F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.**

The rule does not impose more stringent performance requirements on private entities than on public entities.

**G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.**

The rule does not differ from any applicable federal regulation or statute.

**H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.**

There are no other applicable laws.